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## Randomized clinical trial on the survival of lithium disilicate posterior partial restorations bonded using immediate or delayed dentin sealing after 3 years of function

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**Abstract:** **OBJECTIVES** The survival and success rate and the quality of survival of partial ceramic restorations bonded employing Immediate (IDS) or Delayed Dentin Sealing (DDS) in vital molar teeth were evaluated in a randomized clinical trial with within-subject comparison study. **MATERIALS AND METHODS** 30 patients received two lithium disilicate ceramic (IPS-e.max press, Ivoclar Vivadent) partial restorations on vital first or second molar teeth (N = 60). The two teeth randomly received either IDS (test group, n = 30) or DDS (control group, n = 30). Partial ceramic restorations were luted (Variolink Ultra, Ivoclar Vivadent) two weeks after preparation. Evaluations were performed at 1 week, 12 months and 36 months post-operatively, using qualitative (FDI) criteria. Representative failures were evaluated microscopically (SEM) and by means of simplified qualitative fractography analysis. **RESULTS** One absolute failure occurred in the DDS group due to (secondary) caries. The overall survival rate according to Kaplan-Meier after 3 years was 98.3% (FDI criteria score 1-4, n = 59) and the overall success rate was 85% (FDI criteria score 1-3, n = 51), with no significant difference between restorations in the IDS and DDS group (p = 0.32; Kaplan-Meier, Log Rank (Mantel-Cox), CI = 95%). For the quality of the survival, no statistically significant differences were found between IDS and DDS (p = 0.7; Kaplan-Meier, Log Rank (Mantel-Cox), CI = 95%) restorations on any follow-up timepoints for any of the FDI criteria (Wilcoxon, McNemar, p > 0.05). **CONCLUSION** Adhesively luted partial ceramic restorations in vital molar teeth have a good prognosis, however IDS did not show any differences in success and survival rates after 3 years of function.

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# **Randomized Clinical Trial on the Survival of Lithium Disilicate Posterior Partial Restorations Bonded Using Immediate or Delayed Dentin Sealing Under 3 Years of Function**

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**Running title:** Immediate and delayed dentin sealing effect on survival of partial restorations

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## SUMMARY

The survival and the quality of survival of partial ceramic restorations bonded employing Immediate (IDS) or Delayed Dentin Sealing (DDS) in vital molar teeth was evaluated in a randomized clinical trial with within-subject comparison study. Between December 2013 and March 2016, a total of 30 patients (13 women, 17 men; mean age: 54 years) received two lithium disilicate ceramic (IPS-e.max press, Ivoclar Vivadent) partial restorations on vital first or second molar teeth (N=60). Partial preparations were performed on all teeth and the two teeth randomly received either IDS (test group, n=30) or DDS (control group, n=30). Partial ceramic restorations were luted (Variolink Ultra, Ivoclar Vivadent) two weeks after preparation. Evaluations were performed at 1 week, 12 months and 36 months post-operatively, using qualitative criteria. Restorations with flaws were evaluated using SEM. Success rate of the restorations after 36 months was 83.3% (Kaplan-Meier), with no significant difference between restorations in the IDS and DDS group. Nine restorations presented with shortcomings, 5 with DDS and 4 with IDS, leading to an overall survival rate of 98.3%. No statistically significant differences were found between IDS and DDS restorations on any follow-up timepoints for any of the Hickel criteria. One absolute failure occurred in the DDS group due to (secondary) caries. Adhesively luted partial ceramic restorations in vital molar teeth have a good prognosis but do not benefit from IDS with respect to success and survival rates after 3 years of function.

**Key words:** Adhesion, Immediate Dentin Sealing, Lithium Disilicate, Randomized Clinical Trial, Partial Restorations, Survival

## INTRODUCTION

Biomechanically or aesthetically compromised teeth can be restored with partial ceramic indirect restorations. Due to advances in adhesive technologies and ceramic materials it is possible to restore teeth at a limited biological price saving sound tooth tissue. The durability of these partial ceramic restorations relies heavily on the adhesive strength of the resin luting cement to the ceramic restoration and to the tooth surface but also on the ceramic material that is used.

Currently numerous ceramic materials are available for fabricating indirect partial restorations.<sup>1,2</sup> Glass ceramics comprise a vitreous and crystalline phase in which a glassy matrix could be etched optimizing the adhesive strength of these materials.<sup>3-5</sup> In contrast, crystalline ceramics, alumina and zirconia, have minimal or practically no vitreous phase.<sup>3,5</sup> These materials differ in mechanical properties which raises the question what material is best suited for the heavily loaded posterior region. A recent meta-analysis on this subject<sup>3</sup> indicated that the type of ceramic material (feldspathic porcelain vs. glass-ceramic), study design (retrospective vs. prospective), follow-up time (5 vs. 10 years), and study setting (university vs. private clinic) did not affect the survival rate. Estimated survival rates for glass-ceramics and feldspathic porcelain varies between 92% and 95% at 5 years and 91% at 10 years. Failures were related to fractures (4%), endodontic complications (3%), secondary caries (1%) and debonding (1%).<sup>3</sup> However, long-term data comparing survival and success of various types of all-ceramic crowns are lacking.<sup>6</sup>

Adhesion to dentin in particular remains a clinical challenge in clinical dentistry to date. Immediate Dentin Sealing (IDS) has been suggested as an alternative to conventional adhesive luting, also referred to as Delayed Dentin Sealing (DDS).<sup>7-13</sup> With IDS, a thin layer of adhesive resin is applied immediately after tooth preparation and prior to impression taking, whereas with DDS, the adhesive resin layer is applied just before luting the restoration. IDS has been extensively studied and significantly improved over the years with positive results with respect to bond strength, gap

formations, bacterial leakage, and post-cementation hypersensitivity.<sup>7-10,13-22</sup> However, randomized controlled trials on IDS need to be performed, and consequently it is unknown if IDS is a beneficial procedure, preventing failures in partial indirect restorations.<sup>14</sup>

Therefore, the objective of this study is to evaluate the survival and the quality of survival of lithium disilicate posterior partial restorations bonded using immediate or delayed dentin sealing over a 3-year follow up period. The tested null hypotheses were that there would be no significant differences in success and survival rate and the quality of survival between partial indirect ceramic restorations bonded with either IDS or DDS.

## **METHODS AND MATERIALS**

### **Study Design**

Between December 2013 and May 2016, a total of 30 patients (13 women, 17 men; mean age: 54 years) with an indication for two indirect partial ceramic restorations on first or second vital molar teeth were recruited. The inclusion criteria were the following: physically and psychologically able to tolerate conventional restorative procedures; good oral hygiene; presence of intact buccal wall of the tooth; normal response on cold test; possibility to apply rubber dam; presence of the antagonistic tooth; and willingness of the patient to return for follow-up examinations.

The two teeth randomly received either IDS (test group, n=30) or DDS (control group, n=30) through randomization software ([www.randomizer.org](http://www.randomizer.org)). Hence, the study can be characterized as a randomized controlled, single blind clinical trial with within-subject comparison. A consort flow chart showing the enrollment, intervention allocation, follow-up, and data analysis is presented in Figure 1. The study was approved by the Medical Ethics Committee of the University Medical Center Groningen, The Netherlands (ABR number: NL 45130) and registered in the Clinical Trial Register of the US National Library of Medicine (NCT03443583). All patients were provided with informed consent. Distribution of restorations and extension of the restorations are presented in Table 1.

## **Tooth preparation**

The brands, types, manufacturers, chemical compositions and batch numbers of the main materials used in this study are listed in Table 2. After isolating the teeth with rubber dam (Hygenic Dental dam, Coltène/Whaledent Inc., Ohio, USA) the existing restorations were removed. Students executed tooth preparation and luting of the restoration in their first, second or third year of their dentistry masters' closely supervised by one dentist. The outline configuration was a butt shoulder, prepared using diamond burs and specific inserts for inlay preparations in an ultrasonic handpiece (SONICflex prep ceram, KaVo GmbH, Biberach/Riss, Germany). All internal angles were smoothed to reduce stress concentration. The cusps were covered (1.5 mm) if the remaining tooth structure wall was less than 2 mm thick from its occlusal aspect or when the outline of the restoration would be in an area with static or dynamic antagonist contacts. Slight divergence with an angle of 100 to 120° between the proximal cavity walls and the prospective proximal inlay surfaces were provided. The dental technician blocked out any incidental undercuts in the teeth that were allocated to the control group (DDS), the remaining cases were compensated for by the IDS.

The teeth on the test group received IDS (Clearfil SE Primer and Adhesive, Clearfil Majesty Flow, Kuraray) immediately after exposure of dentin (table 3a). Electrosurgery was performed in cases where retraction of the gingiva was required for proper impression making. Impressions were made using a silicone impression material (Heavy and Ultra Light body Aquasil, Dentsply, Mildford, USA) using an individually designed acrylic impression tray. Temporary restorations were then made chair-side using a chemically polymerized resin material (Protemp, 3M ESPE, Neuss, Germany) and cemented using polycarboxylate cement (Durelon, 3M ESPE, Minn, USA).

## **Luting**

One dental technician fabricated all lithium disilicate restorations (IPS e.max press, Ivoclar Vivadent, Schaan, Liechtenstein) following manufacturer instructions. Restorations were glazed at low



temperatures applied to the restoration after construction (FLUO IPS e.max Ceram Glaze paster, Ivoclar Vivadent). Two weeks after preparation, the temporary cement was removed from the teeth with an ultrasonic tip and a scaler. The sequence of the different tooth conditioning and restoration procedures, before luting are presented in Tables 3a-b and 4. The adhesive procedure differed between the test and control group, as outlined in these tables. All the partial restorations were luted using a heated (55°C) dual-polymerized luting composite (Variolink Ultra, Ivoclar Vivadent). Restorations were placed initially under slight pressure where the excess material was removed immediately from the margins with a probe, a scaler and dental floss (Oral-B, Rotterdam, The Netherlands). After increasing the pressure, the final excess composite was manipulated against the tooth in order to prevent marginal gaps. The restorations were photo-polymerized ( $>1.000 \text{ mW/cm}^2$ , Bluephase Style, Ivoclar Vivadent) for 40 seconds from 3 sides and this was repeated after the application of glycerin gel (K-Y Johnson & Johnson, Sezanne, France). Occlusion and articulation was checked carefully using a 40- $\mu\text{m}$  carbon paper (Bausch, Cologne, Germany). The margins of the restorations were finished using a scaler and an ultrasonic device (EVA-handpiece 7LP in combination with a 61 LG, KaVo GmbH) and polished using ceramic polishers (CeraGloss blue and yellow, Edenta, Argau, Switzerland). Intra-oral radiograph was then made in order to check for excess composite in the cervico-approximal region.

## **Evaluation**

Restorations were evaluated at baseline (1 week after luting of the restorations) and thereafter at 12 months and 36 months. One observer evaluated the restorations according to the Hickel criteria <sup>23</sup> calibrated by the e-calib web-based training ([www.e-calib.info](http://www.e-calib.info)). The Hickel criteria are used to measure the quality of survival and determining the success or survival of a restoration. Restorations without any major adverse effects scored 1-3 on Hickel criteria and were considered as a success. Restorations with a score 4 on any of the Hickel criteria were considered repairable failures and considered to have survived. Restorations with a score 5 on Hickel criteria were non-reparable

failures and were considered as absolute failures. With Hickel criteria the most severe score would prevail. The proximal contact points were checked by passing waxed dental floss (Johson&Johnson, Sezanne) through the interdental space. Restorations were visually (2.3x magnification loops, Examvision, Rotterdam, The Netherlands) inspected with a dental mirror and probe. Patients were instructed to call if any kind of failure occurred. Digital photographs (1:1) and intra-oral radiographs were made after placement of the restorations and during follow-up sessions.

### ***SEM (Scanning Electron Microscopy)***

In case of any failure an impression (Ultra Light and Heavy body Aquasil, Dentsply, Mildford, USA) was made from the failure site after cleansing the surface with absorbent paper and hypochlorite 0.5%. Impressions were poured with cold mounting epoxy resin (EpoxyCure, Buehler, IL, USA) which was subsequently sputter-coated with a 3 nm thick layer of gold (80%) / palladium (20%) (90 s, 45mA; Balzers SCD 030, Balzers, Liechtenstein) and analysed using cold field emission Scanning Electron Microscopy (SEM) (LEO 440, Electron Microscopy Ltd, Cambridge, United Kingdom).

### **Statistical Analysis**

Statistical analysis was performed using SPSS 22.0 software for Windows (SPSS Inc., Chicago, IL, USA). Data were analyzed using Kaplan-Meier (Log Rank (Mantel-Cox)) tests to obtain the overall success, survival and failure rates in relation to observation time, and Wilcoxon test and McNemar test were used to test differences in the overall quality of survival. The alpha level was set at 0.05 in all tests.

## RESULTS

After 36 months no dropouts were experienced, 60 indirect posterior restorations (IDS, n = 30; DDS, n = 30) were evaluated. Mean observation time was 37.6 months (SD 2.9 months, min. 32 months, max. 43 months). Seventeen men and 13 women were included. The distribution of the location of the restorations is overviewed in table 1.

The overall success rate (Hickel score 1-3, restorations without any adverse effects, n=50) after 36 months is 85%, not different for the IDS and DDS group (86.7% versus 83.3%, p=0.7; Kaplan-Meier, Log Rank (Mantel-Cox), CI=95%).

The overall survival rate (Hickel score 1-4, n=59) is 98.3% after 36 months. The survival rates for IDS and DDS were 100% and 96.7% respectively (not significantly different, p=0.32; Kaplan-Meier, Log Rank (Mantel-Cox), CI=95%). Following Hickel criteria score 4 (table 5, figure 7) relative failures occurred in the DDS group (n=5; tooth chipping n=3, periodontal complications n=1 and fracture n=1) and in the IDS group (n=4; periodontal complications n=1, secondary caries n=1, debonding n=1, excessive wear n=1). Tooth chipping with dentin exposure (figure 2) after 12 months was seen in a patient with severe teeth grinding (and scored again after 36 months in the same patient), the other chipping failure was a small fragment on an occlusal buccal cusp. Both periodontal complications (IDS and DDS) occurred in the same patient. The fracture (figure 3) originated after 36 months on a bearing cusp and part of the restoration. It could be repaired with a composite material. The debonding failure was a complete adhesive failure between the luting agent and the restoration and occurred 14 months after luting (figure 4). After cleaning the luting surface and removing the composite from the restoration surface, the restoration was replaced using the same adhesive protocol. Excessive wear was seen in a patient with severe teeth grinding (figure 5). In general, restorations scored a duller surface after 36 months compared to 1 week. Some patients (n=5) experienced some postoperative sensitivity after 1 week, but this had resolved at 12 months. No patients reported tooth hypersensitivity after 36 months.

One absolute failure had occurred in the DDS group (secondary caries, figure 6). The secondary caries developed in a medically compromised patient whose oral hygiene had seriously deteriorated, resulting in deep caries, imposing the prognosis of this tooth.

Patients did not call or come in for any kind of failure. All failures were noted at the planned follow-up moments.

## **DISCUSSION**

In this clinical trial the performance of partial ceramic restorations bonded employing Immediate (IDS) or Delayed Dentin Sealing (DDS) in the same patient were compared. Based on non-significant differences in the success and survival rates and the quality of survival with IDS and DDS, the null hypothesis could not be rejected. The results cover up a period of 36 months. All absolute and relative failures were left unnoticed by the patient, hence were observed at the scheduled recall visit. Consequently, the exact time of occurrence could not be registered. According to the Hickel criteria <sup>23</sup> a score 4 or 5 is considered unacceptable and the restoration should be modified or remade. In this study, a score 4 is considered a relative failure due to the ability to repair the restoration and is defined as survival. Repaired restorations can be further monitored and evaluated. <sup>24</sup> A score 5 is considered an absolute failure due to the impossibility to repair this failure.

The number of absolute failures was limited; one restoration presented with secondary caries and had to be extracted. Two patients showed very poor oral hygiene despite regular adjustments during dental-checks ups every 6 months. Unfortunately this resulted in caries during follow-up. One tooth with secondary caries resulted in a relative failure and the other in an absolute failure. Depending on the location and the accessibility of the cavity caries results in an absolute or a relative failure. <sup>24</sup> Secondary caries develops mainly on the proximal gingival floor of class II restorations, usually being independent of the restorative material. <sup>25-27</sup>

Two relative failures occurred in one patient with severe teeth grinding. He reported not to have used the provided splint at night. The cohesive strength of ceramics proved insufficient for this (and possibly also others) individuals with parafunctional habits <sup>28</sup> and thus a splint is indicated for such patients. One failure in this patient being excessive wear and one being tooth chipping (figure 4 and 5). A possible explanation for the occurrence of tooth chipping is that the preparation design had not been uniform. The thickness of the ceramic was not similar all over the tooth, leading to a variation in wall height and resulting in a higher stress concentration. <sup>29</sup> This is also considered a probable cause of failure in figure 3 (right) because the SEM image shows an abrupt geometry variation; a very thick block of ceramic to a very thin part of ceramic on a very small distance. This results in an unfavorable stress distribution that could create a fracture site. In both failures in the patient with severe teeth grinding a fracture line is seen in the ceramic (figure 2 and 5) and received a score 3 for Hickel criteria on fracture of material and retention. Cracks are acceptable as long as there are no clinical symptoms present. <sup>24</sup> A small fracture in the ceramic is not always a problem as long as the location and adhesive is supportive and thus the stress can be distributed enough to prevent the restoration from catastrophic failure. <sup>30</sup> Especially in patients with severe teeth grinding, compromised design of the restoration or preparation is less forgiving. One of the relative failures was due to a fracture (figure 3). Here, the stress distribution may lead to a problem due to design of the restoration (thin isthmus). Because the mesio-lingual cusp was left too high and too thin, cuspal deflection may have lead to the fracture. Cuspal coverage is commonly recommended in order to protect the weakened tooth structure. <sup>31</sup> The benefit of a full cuspal coverage design (onlay) can be explained by the amount of the remaining tooth structure <sup>32</sup> , resulting in favorable distribution of stresses in teeth and reduces risk of fracture. <sup>33</sup> The discolored part of the wall indicates leakage of the restoration, probably due to cuspal deflection the bonding disrupted in this part. Preparation margins should have correct configuration to prevent chippings and cracks from and in the ceramic leading to crack propagation. <sup>34</sup> Fracture initiation sites are often created by parts in the restoration where the ceramic

is very thin or where there is an air bubble present in the ceramic material.<sup>29,34</sup> Avoiding marginal ridge contact is recommended for these kind of restorations. In partial ceramic restorations IDS is thought to improve the adhesion resulting in improvement of the fracture strength.<sup>35</sup> Although we did not find any statistically significant difference in the performance of partial restorations using IDS or DDS some failures only occurred in the DDS group; tooth chipping and fractures. Further follow-up is needed to support the in vitro results and to see if IDS could indeed prevent some failures in partial indirect restorations on the mid- and long-term analysis.

In the debonding failure after 14 months (figure 4), the disto-buccal part of the restoration showed a discolored part which could indicate that there was not enough luting agent. Early failures are commonly related to technical flaws and not as a consequence of fatigue. During luting of this restoration, the cement was already partly light-cured by environment light, compromising the initial fit of the restoration. This part of the cement had to be removed and the procedure had to be redone. This procedure eventually resulted in insufficient marginal sealing.

Two periodontal failures were in a single patient as a result of poor oral hygiene during the follow-up period and to lack of regular dental check-ups. The increased pocket depths are not likely to have high impact on the longevity of the restoration itself, but rather reflects the functional oral environment. The restorations of this patient were not in direct contact with the periodontal tissues.

The survival rate of the restorations in this study (98.3%) is comparable to that in other studies but the success rate (85%) is somewhat lower than reported elsewhere.<sup>3</sup> The former may reflect the (initially limited) experience of the team in providing this type of restorations as training and experience is presumed to affect the outcome. No endodontic complications were seen while this is a common failure in other studies (3%).<sup>3</sup> This finding reflects the minimal invasive preparation design as the amount of tooth structure reduction is considered to be an important factor affecting postoperative tooth sensitivity.<sup>32</sup>

Clinically it is difficult, to differentiate between gaps at the interface between luting material and hard tissues, and between luting material and restoration in compromised restorations. SEM examination was considered quite useful in assessing these aspects and is recommended for other clinical survival studies as well.

## **CONCLUSIONS**

Adhesively luted, partial ceramic restorations in vital molar teeth have a good prognosis but do not benefit from IDS with respect to success and survival rates after 3 years of function.

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## **Conflict of interest**

The authors' institutions supported this study. The authors declare that they have no conflicts of interest and that they did not have any commercial interest in any of the materials used in this study.

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## Captions to the tables and figures:

### Tables:

**Table 1** Distribution of restored teeth and extension of the restorations in the maxilla and mandible in the test (Immediate Dentin Sealing-IDS) and control (Delayed Dentin Sealing-DDS) group.

**Table 2** The brands, types, manufacturers, chemical compositions and batch numbers of the major materials used in this study.

**Table 3a-b** Clinical protocol for the **a)** test group (Immediate Dentin Sealing-IDS), **b)** control group (Delayed Dentin Sealing-DDS).

**Table 4** Clinical protocol for luting procedures of the ceramic restorations.

**Table 5** Summary of Hickel criteria evaluation at 1 week, at 12 months and at 36 months.

### Figures:

**Figure 1** Consolidated Standards of Reporting Trials (CONSORT) 2010 flow diagram.

**Figure 2** Images of tooth chipping with dentin exposure.

**Figure 3** Images of fracture failure.

**Figure 4** Images of debonding failure.

**Figure 5** Images of excessive wear of the ceramic and fracture lines in the ceramic.

**Figure 6** X-ray presenting secondary caries.

**Figure 7** Kaplan-Meier curve of the relative failures of partial ceramic restorations bonded employing either Immediate (IDS) or Delayed Dentin Sealing (DDS) (IDS: 100%, n = 30, events n= 4; DDS: 96.7%, n = 30, events n = 5).

Test group	Molars (n)					Total (N)
	0 cusps replaced	1 cusp replaced	2 cusps replaced	3 cusps replaced	4 cusps replaced	
Maxilla (n)	2	4	5	2	6	19
Mandible (n)	2	1	1	4	3	11
Total (N)	4	5	6	6	9	30

Control group	Molars (n)					Total (N)
	0 cusps replaced	1 cusp replaced	2 cusps replaced	3 cusps replaced	4 cusps replaced	
Maxilla (n)	5	1	1	2	5	14
Mandible (n)	2	3	5	2	4	16
Total (N)	7	4	6	4	9	30

**Table 1.** Distribution of restored teeth and extension of the restorations in the maxilla and mandible in the test (Immediate Dentin Sealing-IDS) and control (Delayed Dentin Sealing-DDS) group.

Brand	Type	Manufacturer	Chemical composition	Batch-number
IPS-e.max Press	Pressable ceramic	Ivoclar Vivadent, Schaan, Liechtenstein	SiO <sub>2</sub> , LiO, K <sub>2</sub> O, P <sub>2</sub> O <sub>5</sub> , ZrO <sub>2</sub> , ZnO.	-
Variolink Ultra Catalyst / Base	Dual-cure luting composite	Ivoclar Vivadent	Ytterbium trifluoride, Bis-GMA, urethane dimethacrylate, methylene glycol dimethacrylate, dibenzoyl peroxide, titanium dioxide	S27220/ S06644
Clearfil SE Primer	Adhesive primer	Kuraray CO., Ltd., Osaka, Japan	HEMA, hydrophilic dimethacrylate, water, photo-initiator	2U0022
Clearfil SE Bond	Adhesive resin	Kuraray CO., Ltd.	MDP, HEMA, bis-GMA, hydrophilic dimethacrylate, water, photo-initiator, silanated colloidal silica	2T003
Excite F DSC	Single component adhesive	Ivoclar Vivadent	Phosphonic acid acrylate, dimethacrylates, hydroxyethyl methacrylate, highly dispersed silicon dioxide, ethanol catalysts, stabilizers, fluoride	S36470
CoJet-sand	Blast-coating agent	3M ESPE, Minn, USA	Aluminium trioxide particles Coated with silica, 30 µm	446317/ 534151
ESPE-Sil	Silane coupling agent	3M ESPE	Ethyl alcohol, 3-methacryloxypropyl-trimethoxysilane, ethanol	518272
Monobond Plus	One component primer	Ivoclar Vivadent	Ethanol, 3-trimethoxysilylpropyl-methacrylate, methacrylated phosphoric acid ester	S31153
IPS Ceramic etch	Hydrofluoric acid	Ivoclar Vivadent	<5% Hydrofluoric acid	S26140
IPS Neutralizing powder	powder	Ivoclar Vivadent	Sodium carbonate	S34285
Ultra-etch	35% Phosphoric acid	Ultradent, South Jordan UT, USA	35% phosphoric acid	130910
Clearfil Majesty Flow	Photo-cure composite	Kuraray CO.	Triethylene glycol dimethacrylate, Hydrophobic aromatic dimethacrylate, Silanated barium glass filler, Silanated silica filler, di-Camphorquinone	00339BA
Glycerin gel	K-Y* lubricating gel	K-Y, Johnson & Johnson, Sezanne, France	Purified water, Glycerin, Methylparaben, Propylparaben, Propylene Glycol, Hydroxyethylcellulose, Disodium Phosphate, Sodium Phosphate, Tetrasodium, EDTA	1233V

**Table 2.** The brands, types, manufacturers, chemical compositions and batch numbers of the materials used.

<b>Visit 1: Tooth preparation</b>	<b>Working time (s)</b>
1.1 Tooth preparation	
1.2 Apply Clearfil SE Primer, active brushing motion	20
1.3 Air suction	
1.4 Apply Clearfil SE Adhesive, active brushing motion	10
1.5 Air-thin	10
1.6 Photo-polymerize	10
1.7 Apply flowable resin (Clearfil Majesty Flow)	
1.8 Photo-polymerize	40
1.9 Apply glycerin gel	
1.10 Photo-polymerization at buccal, oral and proximal sites	40 each
1.11 Rinse until clean surface	
1.12 Clean the enamel outline with a rubber-point or a bur	
1.13 Make impression	
<b>Visit 2: Cleaning and conditioning of the tooth prior to luting</b>	
2.1 Clean tooth surface (EMS)	
2.2 Silica-coat (CoJet-sand) the IDS	2-3
2.3 Acid etch enamel	30
2.4 Rinse	30
2.5 Dry	
2.6 Apply silane (ESPE-Sil) on the IDS	60
2.7 Apply adhesive resin (Excite F DSC)	
2.8 Apply resin cement (Variolink Ultra) on the tooth	
2.9 Place the partial restoration onto the tooth	
2.10 Remove excess cement	
2.11 Photo-polymerize at buccal, oral and proximal sides	40 each
2.12 Apply glycerin gel	
2.13 Photo-polymerize at buccal, oral and proximal sides	40 each

**Table 3-a.** Clinical protocol for the test group (Immediate Dentin Sealing-IDS).

Visit 1: Tooth preparation	Working time (s)
1.1 Tooth preparation	
1.2 Make impression	
Visit 2: Cleaning and conditioning of the tooth prior to luting	
2.1 Clean tooth surface (EMS)	
2.2 Acid etch enamel and dentin	30
2.3 Rinse	30
2.4 Dry	
2.5 Apply adhesive resin (Excite F DSC)	
2.6 Apply resin cement (Variolink Ultra) on the tooth	
2.7 Place the partial restoration onto the tooth	
2.8 Remove excess cement	
2.9 Photo-polymerize at buccal, oral and proximal sides	40 each
2.10 Apply glycerin gel	
2.11 Photo-polymerize at buccal, oral and proximal sides	40 each

**Table 3-b.** Clinical protocol for the control group (Delayed Dentin Sealing-DDS).

Visit 2: Luting procedures of the ceramic restorations	Working time (s)
2.1. Apply hydrofluoric acid etch (IPS Ceramic etch)	20
2.2. Rinse and neutralize	60
2.3. Rinse and dry	
2.4. Ultrasonically clean in distilled water	300
2.5. Dry	
2.6. Apply silane (Monobond Plus) one coat and wait its reaction	60
2.7. Apply adhesive resin (Excite F DSC)	
2.8. For the subsequent procedures, follow step 2.8 in Table 3a or step 2.6 in Table 3b.	

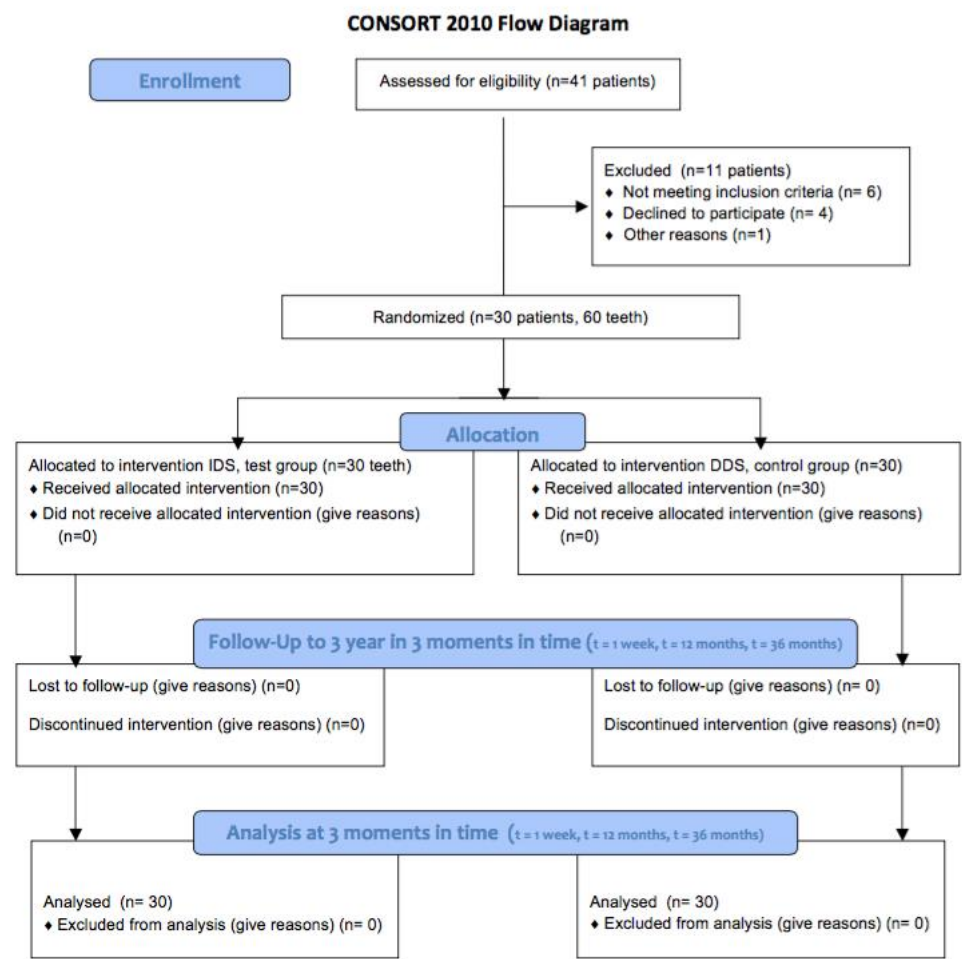
**Table 4.** Clinical protocol for luting procedures of the ceramic restorations.

Hickel - criteria		IDS			DDS		
		1 week	12 months	36 months	1 week	12 months	36 months
<b>A. Esthetic Properties</b>							
1. Surface lustre	1	29	13	9	29	9	7
	2	1	10	14	1	11	13
	3	-	7	7	-	10	10
	4	-	-	-	-	-	-
	5	-	-	-	-	-	-
2. Staining surface / margin	1	30	28	21	30	27	21
	2	-	1	7	-	2	8
	3	-	1	2	-	1	1
	4	-	-	-	-	-	-
	5	-	-	-	-	-	-
3. Color match and translucency	1	24	21	20	28	26	23
	2	5	5	6	1	1	4
	3	1	4	4	1	3	3
	4	-	-	-	-	-	-
	5	-	-	-	-	-	-
4. Esthetic anatomical form	1	30	30	30	30	30	30
	2	-	-	-	-	-	-
	3	-	-	-	-	-	-
	4	-	-	-	-	-	-
	5	-	-	-	-	-	-
<b>B. Functional properties</b>							
5. Fracture of material and retention	1	28	26	27	30	29	26
	2	2	2	-	-	-	2
	3	-	1	3	-	1	-
	4	-	-	-	-	-	2
	5	-	1	-	-	-	-
6. Marginal adaptation	1	26	23	17	28	20	16
	2	3	7	12	2	9	13
	3	1	-	1	-	1	1
	4	-	-	-	-	-	-
	5	-	-	-	-	-	-
7. Occlusal contour wear qualitatively / quantitatively	1	30	29	28	30	29	29
	2	-	-	1	-	-	-
	3	-	1	-	-	1	1
	4	-	-	1	-	-	-
	5	-	-	-	-	-	-
8. Approximal anatomical form contact point / contour	1	-	30	30	-	30	30
	2	-	-	-	-	-	-
	3	-	-	-	-	-	-
	4	-	-	-	-	-	-
	5	-	-	-	-	-	-
9. Radiographic examination	1	29	29	28	28	29	29
	2	1	1	2	2	1	1
	3	-	-	-	-	-	-
	4	-	-	-	-	-	-
	5	-	-	-	-	-	-
10. Patient's view	1	25	30	30	26	30	29
	2	-	-	-	-	-	-
	3	5	-	-	4	-	-
	4	-	-	-	-	-	1
	5	-	-	-	-	-	-
<b>C. Biological properties</b>							
11. Postoperative (hyper-)sensitivity and tooth vitality	1	28	30	30	27	30	30
	2	1	-	-	3	-	-
	3	1	-	-	-	-	-
	4	-	-	-	-	-	-
	5	-	-	-	-	-	-
12. Recurrence of caries, erosion, abfraction	1	30	30	28	30	30	27
	2	-	-	-	-	-	1
	3	-	-	1	-	-	1
	4	-	-	-	-	-	-
	5	-	-	1	-	-	1
13. Tooth integrity (enamel cracks, tooth fractures)	1	29	30	30	30	29	28
	2	1	-	-	-	-	-
	3	-	-	-	-	-	-
	4	-	-	-	-	1	2
	5	-	-	-	-	-	-
14. Periodontal response (compared to a reference tooth)	1	18	19	18	20	19	16
	2	12	7	9	0	8	12
	3	-	3	3	-	2	2
	4	-	1	-	-	1	-
	5	-	-	-	-	-	-
15. Adjacent mucosa	1	23	30	28	26	30	30
	2	7	-	2	4	-	-
	3	-	-	-	-	-	-
	4	-	-	-	-	-	-
	5	-	-	-	-	-	-
16. Oral and general health	1	30	30	30	30	30	30
	2	-	-	-	-	-	-
	3	-	-	-	-	-	-
	4	-	-	-	-	-	-
	5	-	-	-	-	-	-

**Table 5.** Summary of the Hickel criteria evaluation at 1 week, at 12 months and at 36 months.

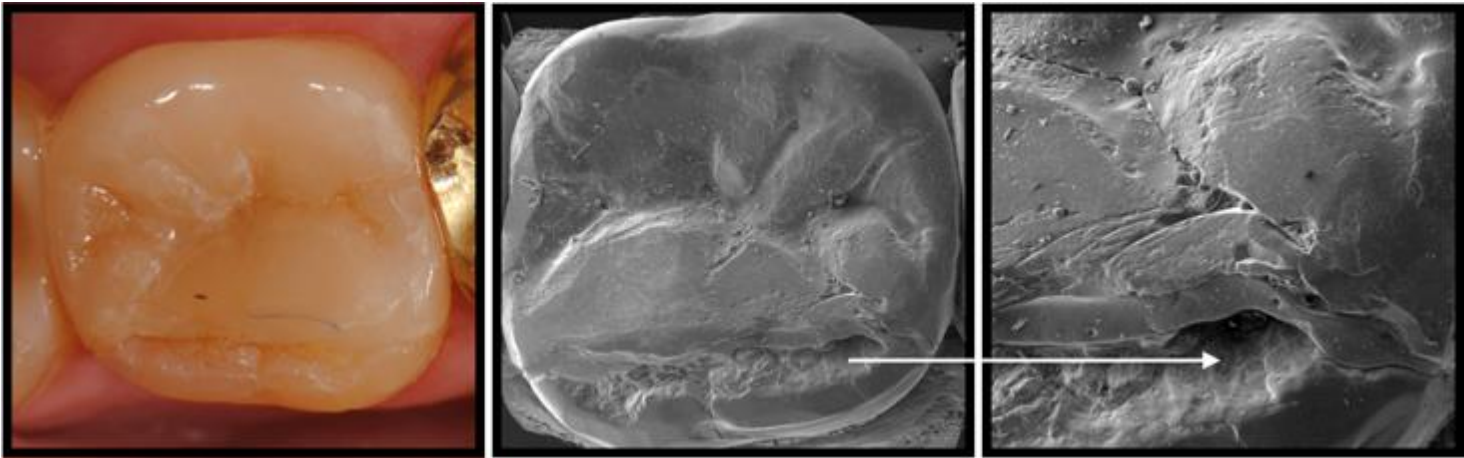
Restorations with Hickel score 1-3 are considered to have succeed. Restorations with Hickel score 4

are considered to have relatively failed and are considered to have survived. Restorations with Hickel score 5 are considered to have absolutely failed.

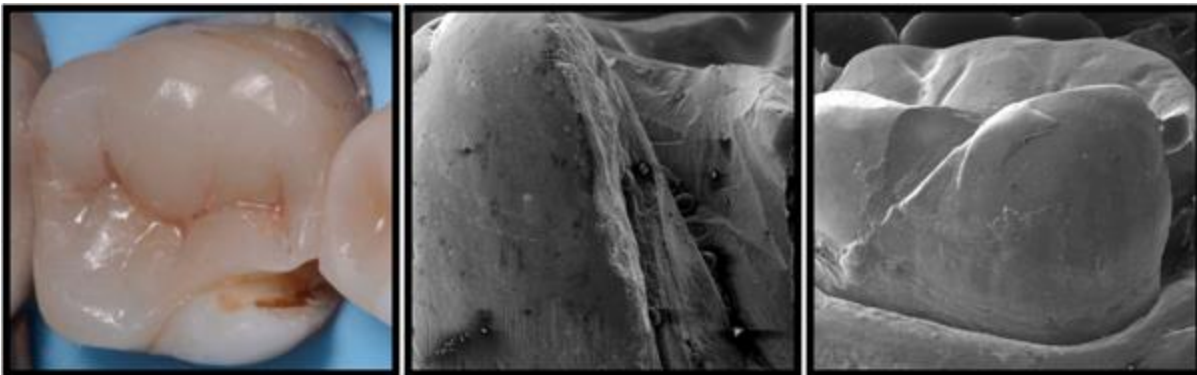


**Fig. 1** Consolidated Standards of Reporting Trials (CONSORT) 2010 flow diagram explaining enrollment, intervention allocation, follow-up and data analysis.

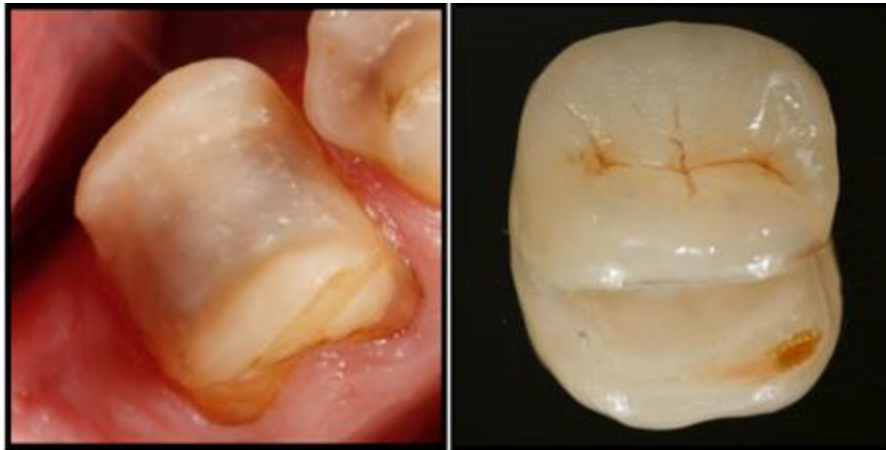




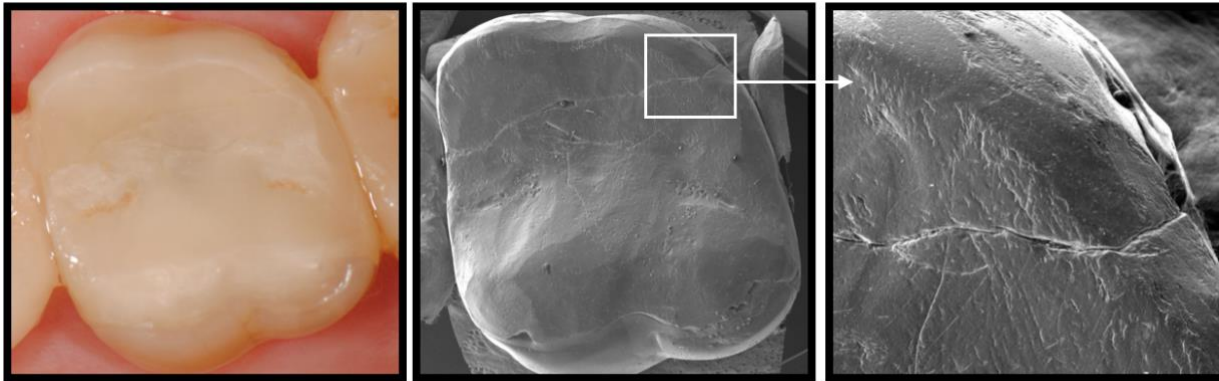
**Fig. 2 (left)** Chipping of tooth 37 with dentin exposure. **(middle)** SEM image of chipping of tooth 37 with dentin exposure. Note the fracture line from buccal to the mesial part. **(right)** Detailed SEM image of the chipping plane. Note the fracture line in the ceramic.



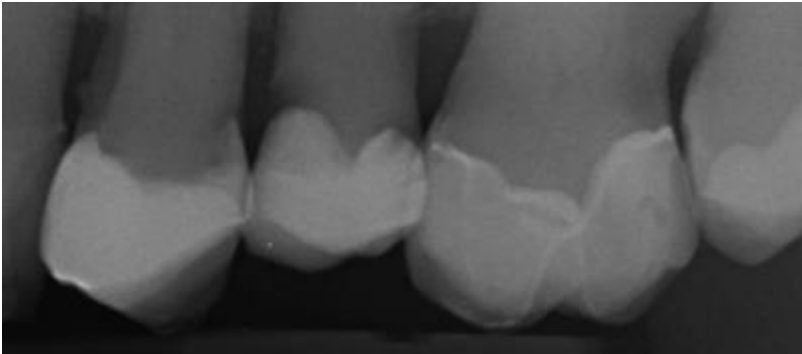
**Fig. 3 (left)** Fracture of the mesio-lingual aspect of tooth 36. Note the discolored dentin part at the inner wall next to a remnant of composite material **(middle)** SEM image of the fracture with the bearing intact cusp on the left side. Fracture visible in the ceramic with a part of the composite still attached to the tooth **(right)** SEM image of the lingual side of the tooth with the fracture in the ceramic on the mesio-lingual side.



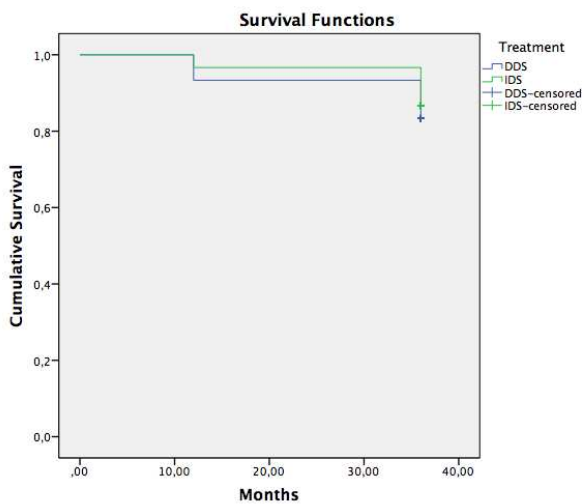
**Fig. 4 (left)** Tooth surface after debonding of restoration 36, note the intact IDS/composite layer. **(right)** Restoration debonding surface. Note the discolored disto-buccal part of the restoration.



**Fig. 5 (left)** Excessive wear on the occlusal part of the restoration 26. Note the fracture line in the ceramic on the buccal side of the restoration. **(middle)** SEM image of restoration 26. Note the excessive wear and the clear fracture line in the ceramic from mesial to distal. **(right)** Detailed SEM image of small bending and branching of the fracture line in the ceramic.



**Fig. 6** Secondary caries at tooth 26, distal aspect. The lesion proved an understatement of the intra-oral size of the cavity. Note also the secondary caries on teeth nrs. 24 and 35.



**Fig. 7** Kaplan-Meier curve of the relative failures of partial ceramic restorations bonded employing either Immediate (IDS) or Delayed Dentin Sealing (DDS) (IDS: 86.7%, n = 30, events n= 4; DDS: 83.3%, n = 30, events n = 5).